

laser-lok 3.0

dental implant system



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laser-lok 3.0

- Two-piece 3mm design offers restorative flexibility in narrow spaces.
- 3mm threadform shown to be effective when immediately loaded.¹
- Implant design is more than 20% stronger than competitor 3.0 implant when loaded.²
- Laser-Lok microchannels create a physical connective tissue attachment.³



BioHorizons is the only company that can claim (FDA-cleared) that its implant surface establishes a physical connective tissue attachment (unlike Sharpey fiber attachment).

This tissue connection:

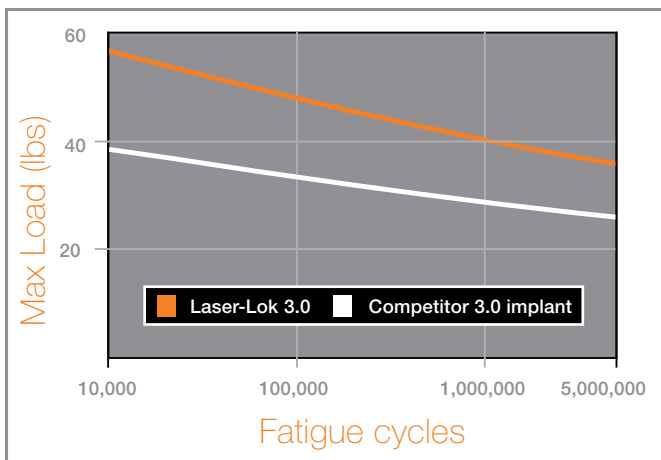
- is functionally oriented,
- inhibits epithelial cell downgrowth and
- enables crestal bone adjacent to the implant to attach and be retained.



Supported by the broadest array of prosthetics.



3mm threadform shown to be effective when immediately loaded.¹
(Image courtesy of Craig Misch, DDS)



Implant design is more than 20% stronger than competitor 3.0 implant²

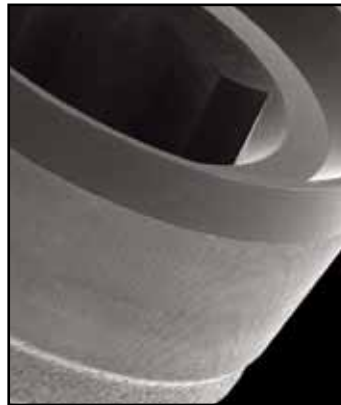


Two-piece 3mm design offers restorative flexibility in narrow spaces.
(Image courtesy of Cary Shapoff, DDS)

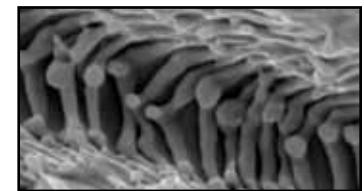
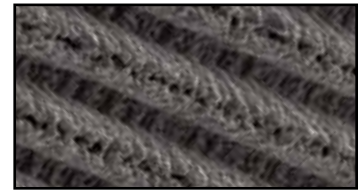
Laser-Lok Technology

Laser-Lok overview

Laser-Lok microchannels is a proprietary dental implant surface treatment developed from over 20 years of research initiated to create the optimal implant surface. Through this research, the unique Laser-Lok surface has been shown to elicit a biologic response that includes the inhibition of epithelial downgrowth and the attachment of connective tissue (unlike Sharpey fibers).^{3,4} This physical attachment produces a biologic seal around the implant that protects and maintains crestal bone health. Implants with Laser-Lok technology have been shown in post-market studies to be more effective than other implant designs in reducing bone loss.^{5,6,7,8}



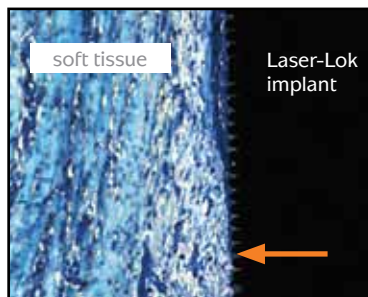
SEM image at 30X showing the Laser-Lok zone on a BioHorizons implant.



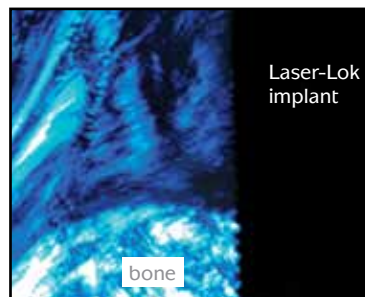
The uniformity of the Laser-Lok microstructure and nanostructure is evident using extreme magnification.

Unique surface characteristics

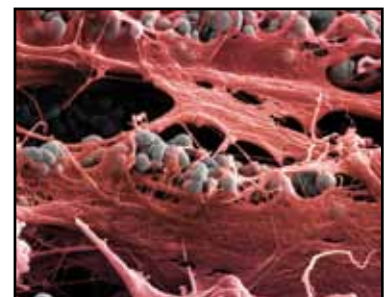
Laser-Lok microchannels is a series of cell-sized circumferential channels that are precisely created using laser ablation technology. This technology produces extremely consistent microchannels that are optimally sized to attach and organize both osteoblasts and fibroblasts.^{9,10} The Laser-Lok microstructure also includes a repeating nanostructure that maximizes surface area and enables cell pseudopodia and collagen microfibrils to interdigitate with the Laser-Lok surface.



Human histology shows the apical extent of the junctional epithelium below which there is a supracrestal connective tissue attachment to the Laser-Lok surface.³



Polarized lights show the connective tissue is functionally oriented.³



Colorized SEM of a dental implant harvested at 6 months post-op shows the connective tissue is physically attached and interdigitated with the Laser-Lok surface.

Different than other surface treatments

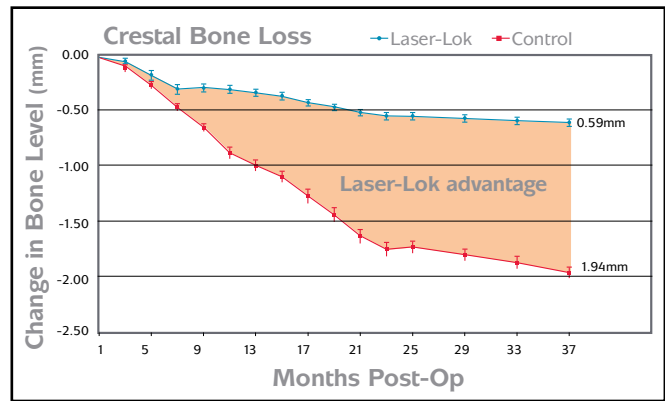
Virtually all dental implant surfaces on the market are grit-blasted and/or acid-etched. These manufacturing methods create random surfaces that vary from point to point on the implant and alter cell reaction depending on where each cell comes in contact with the surface.¹¹ While random surfaces have shown higher osseointegration than machined surfaces,¹² only the Laser-Lok surface has been shown using light microscopy, polarized light microscopy and scanning electron microscopy to also be effective for soft tissue attachment.^{3,13}

The clinical advantage

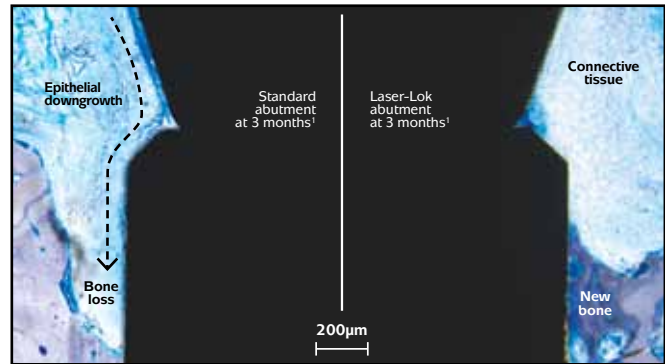
The Laser-Lok surface has been shown in several studies to offer a clinical advantage over other implant designs. In a prospective, controlled multi-center study, Laser-Lok implants, when placed alongside identical implants with a traditional surface, were shown at 37 months post-op to reduce bone loss by 70% (or 1.35mm).⁵ In a retrospective, private practice study, Laser-Lok implants placed in a variety of site conditions and followed up to 3 years minimized bone loss to 0.46mm.⁶ In a prospective, University-based overdenture study, Laser-Lok implants reduced bone loss by 63% versus NobelReplace™ Select.⁷

Latest discoveries

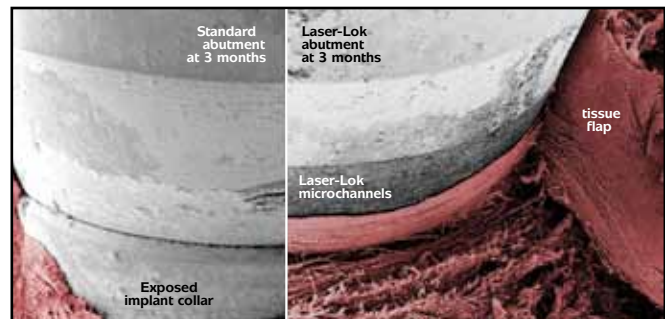
The establishment of a physical, connective tissue attachment (unlike Sharpey fibers) to the Laser-Lok surface has generated an entirely new area of research and development: Laser-Lok applied to abutments. This could provide an opportunity to use Laser-Lok abutments to create a biologic seal and Laser-Lok implants to establish superior osseointegration¹⁰ – a solution that offers the best of both worlds. Alternatively, Laser-Lok abutments could support peri-implant health around implants without Laser-Lok. In a recent study, Laser-Lok abutments and standard abutments were randomly placed on implants with a grit-blasted surface to evaluate the differences. In this proof-of-principle study, a small band of Laser-Lok microchannels was shown to inhibit epithelial downgrowth and establish a connective tissue attachment (unlike Sharpey fibers) similar to Laser-Lok implants.¹³ This time, however, the attachment was established above the dental implant-abutment connection and even on implants with a machined collar.¹³ The resulting crestal bone levels were higher than what was seen with standard abutments and provides some insight into the role soft tissue stability may play in maintaining crestal bone health.



In a 3-year multicenter perspective study, the Laser-Lok surface showed superior bone maintenance over identical implants without the Laser-Lok surface.⁵



Comparative histologies show the biologic differences between standard abutments and Laser-Lok abutments including changes in epithelial downgrowth, connective tissue and crestal bone health.¹³

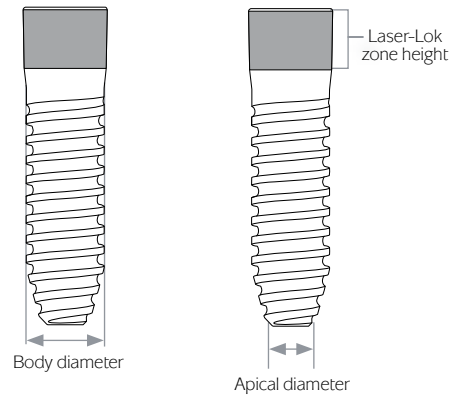


Comparative SEM images show the variation in tissue attachment strength on standard and Laser-Lok abutments when a tissue flap is incised vertically and manually lifted using forceps.¹³

Laser-Lok Technology is available on Laser-Lok 3.0, Tapered Internal, Single-stage & Internal implants

Laser-Lok 3.0 Implants

Body Diameter	3.0mm
Apical Diameter	2.0mm
Laser-Lok Zone Height	2.1mm
Minimum Ridge Width	5.0mm
Minimum Mesial / Distal Space	6.0mm



Implants



- TP3105L** Laser-Lok 3.0 Implant, 10.5mm
- TP312L** Laser-Lok 3.0 Implant, 12mm
- TP315L** Laser-Lok 3.0 Implant, 15mm

Laser-Lok collar with Resorbable Blast Texturing (RBT) on implant body. Packaged with Cover Cap (TP3CC). Titanium Alloy [Ti-6Al-4V].

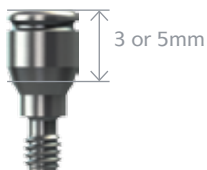
Cover Cap



- TP3CC** Cover Cap

For use during submerged surgical healing. May also be used as a 1 mm Healing Abutment. Hand-tighten with the .050" (1.25mm) Hex Driver. Titanium Alloy [Ti-6Al-4V]. A Cover Cap is included with each implant but can also be ordered separately.

Healing Abutments



- TP3HA3** Healing Abutment, 3mm Height
- TP3HA5** Healing Abutment, 5mm Height

Hand-tighten with the .050" (1.25mm) Hex Driver. Titanium Alloy [Ti-6Al-4V].

SURGICAL INSTRUMENTS



Laser-Lok 3.0 Surgical Kit

TP3KIT
Laser-Lok 3.0 Surgical Kit (complete)
 Includes all instruments shown below.

TP3ST
Laser-Lok 3.0 Surgical Tray with Lid
 Without instruments.

Individual Kit Components



122-200
 Tissue Punch



122-403
 2.0mm Starter Drill
 Extended Shank



122-425
 2.5mm Depth Drill
 Extended Shank



122-425105
 2.5 x 10.5mm
 Depth Drill
 Extended Shank



122-42512
 2.5 x 12mm
 Depth Drill
 Extended Shank



122-42515
 2.5 x 15mm
 Depth Drill
 Extended Shank



TP3CBD
 Crestal Bone Drill



122-900
 Bone Tap



TP3IDH
 Implant-level Driver,
 Handpiece*



TP3IDR
 Implant-level Driver,
 4mm square*



300-351
 .050" (1.25mm) Hex Driver, Long*



144-100 Straight Parallel Pins (2 per kit)

144-200 20° Angled Parallel Pin (1 per kit)

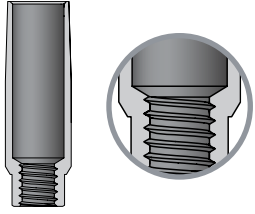


300-400
 Hand Wrench*



130-000
 Ratchet

**instrument o-rings & c-rings wear out over time. If an instrument is no longer held securely by its associated driver, order a replacement ring through Customer Care.
 products shown not to scale*



Laser-Lok 3.0 abutments
 Laser-Lok 3.0 abutments are internally threaded for increased strength. Delivery to the mouth can be achieved by inserting an .050" (1.25mm) Hex Driver into the abutment screw that is pre-assembled into the abutment.

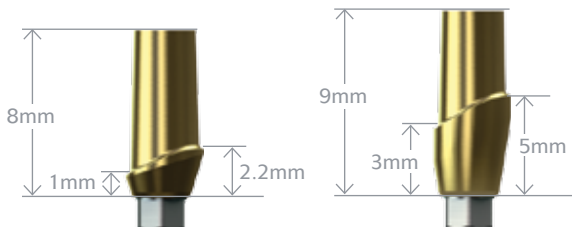
Straight Abutment



TP3SA Straight Abutment

Used to fabricate cement-retained, single- or multiple-unit prostheses. Pre-assembled with Abutment Screw (PXAS). Titanium Alloy [Ti-6Al-4V]. Final torque: 30Ncm.

Straight Esthetic Abutments

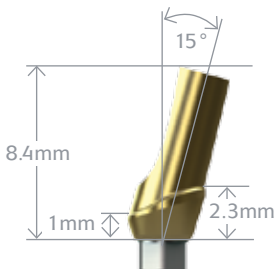


TP3SEA Straight Esthetic Abutment

TP3SEA3 Straight Esthetic Abutment, 3mm Buccal

Used to fabricate cement-retained, single- or multiple-unit prostheses. Pre-assembled with Abutment Screw (PXAS). Titanium Alloy [Ti-6Al-4V]. TiN coated. Final torque: 30Ncm.

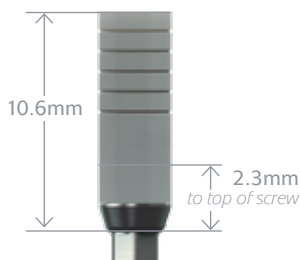
Angled Esthetic Abutment



TP3AEA Angled Esthetic Abutment

Used to fabricate cement-retained, single- or multiple-unit prostheses. Pre-assembled with Abutment Screw (PXAS). Titanium Alloy [Ti-6Al-4V]. TiN coated. Final torque: 30Ncm.

Custom Castable (UCLA) Abutments



TP3CAH 3.0mm Custom Cast Abutment, Hexed

TP3CAN 3.0mm Custom Cast Abutment, Non-hexed

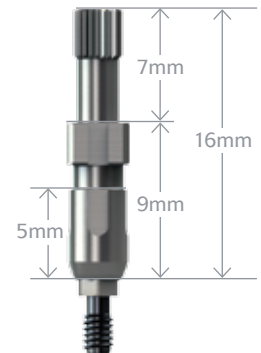
Hexed Custom Cast Abutment used for single-unit screw-retained or custom abutment cement-retained restorations. Non-hexed Custom Cast Abutment used for multiple-unit, screw-retained restorations. Pre-assembled with the Abutment Screw (PXAS). Gold Alloy base with natural acetyl (Delrin® or Pomalux®) sleeve. Final torque: 30Ncm.

Direct Pick-up Copings (Open Tray)

TP3DC Direct Pickup Coping, Hexed

TP3DCN Direct Pickup Coping, Non-hexed

Used to make an open-tray, implant-level, hexed or non-hexed impression.
Packaged with the extended Direct Coping Screw (PXDCS). Titanium Alloy [Ti-6Al-4V].



Implant Analogs

TP3IA Implant Analog

Represents the implant in a laboratory-fabricated, implant-level stone model.
Titanium Alloy [Ti-6Al-4V].

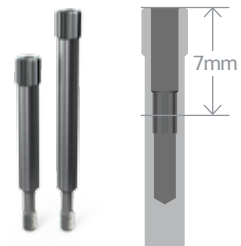


Direct Coping Screws

PXDCS Direct Coping Screw

PXDCSL Direct Coping Screw, Long

The PXDCS is packaged with all Direct Pick-up Copings. May also be used in place of the Abutment Screw (PXAS) when extra length is needed, or to maintain the screw access hole during fabrication of screw-retained provisional prostheses. Up to 7mm can be removed from either screw without losing the hex engagement. Utilizes the .050" (1.25mm) Hex Driver. Hand-tighten or torque to 30 Ncm depending on application. Titanium Alloy [Ti-6Al-4V]. PXDCSL adds 5mm length compared to the PXDCS.



Surgical Driver

150-000 Surgical Driver

Used to drive implants into the osteotomy, particularly in the anterior region. The driver interfaces with the .050" (1.25mm) Hex Driver as well as Bone Tap and the Implant-level Driver, 4mm square.



Adjustable Torque Wrench

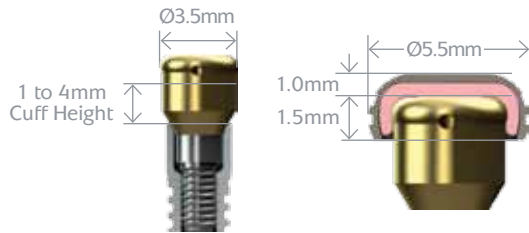
ATW ITL Precise Adjustable Torque Wrench

Ratchet design places both implants and abutments with 9 distinct torque settings (15, 20, 25, 30, 35, 40, 45, 50 and 60 Ncm). A simple twist of the handle locks in precision-engineered torque values and guarantees accuracy and repeatability.



LOCATOR ABUTMENT COMPONENTS

Locator® Abutments



- TP3LA1** **Locator Abutment, 1.0mm Cuff Height**
- TP3LA2** **Locator Abutment, 2.0mm Cuff Height**
- TP3LA3** **Locator Abutment, 3.0mm Cuff Height**
- TP3LA4** **Locator Abutment, 4.0mm Cuff Height**

The Locator Implant Attachment System is designed for use with overdentures or partial dentures retained in whole or in part by dental implants in the mandible or maxilla. Order by Cuff Height to match the height of the gingival tissue. The abutment will extend above the tissue by 1.5mm to allow the Locator Male to seat completely. Order one Locator Male Processing Set for each Locator Abutment (sold in packs of 2 or 10). Locator Abutments are made from Titanium Alloy [Ti-6Al-4V].

Locator Components



LCT

Core Tool

Multi-purpose tool serves as hand driver for seating Locator Abutments onto the implants, seating tool for nylon male inserts and insert removal tool.



LMPP-2

Male Processing Package (2 pack)

Includes: (2) Denture Caps with (2) Black Processing Males; (2) White Block-out Spacers; (2) Clear, (2) Pink and (2) Blue Nylon Males.



LIC

Impression Coping (4 pack)



Square Drive Tool

Used with a torque wrench to seat Locator Abutments.

LSDD-15MM Square Drive Tool (15mm length)

LSDD-21MM Square Drive Tool (21mm length)



LFA-4MM

Female Analog Ø4mm (4 pack)



LAMG

Angle Measurement Guide



LPP

Parallel Post (4 pack)



LRM-G

Extended Range Replacement Male (green)

Retention: 3-4lbs / 1361-1814g, 4 pack



LRM-C

Replacement Male (clear)

Retention: 5lb / 2268g, 4 pack



LRM-R

Extended Range Extra Light Retention Replacement Male (red)

Retention: 1.5lbs / 680g, 4 pack



LRM-P

Light Retention Replacement Male (pink)

Retention: 3lb / 1361g, 4 pack



LBPRM

Black Processing Replacement Male



LRM-B

Extra Light Retention Replacement Male (blue)

Retention: 1.5lb / 680g, 4 pack

SURGICAL MANUAL INTRODUCTION

This Surgical Manual serves as a reference for using the Laser-Lok 3.0 implants and surgical instruments. It is intended solely to provide instructions on the use of BioHorizons products. It is not intended to describe the methods or procedures for diagnosis, treatment planning, or placement of implants, nor does it replace clinical training or a clinician's best judgment regarding the needs of each patient. BioHorizons strongly recommends appropriate training as a prerequisite for the placement of implants and associated treatment.

The procedures illustrated and described within this manual reflect idealized patient presentations with adequate bone and soft tissue to accommodate implant placement. No attempt has been made to cover the wide range of actual patient conditions that may adversely affect surgical and prosthetic outcomes. **Clinician judgment as related to any specific case must always supersede any recommendations made in this or any BioHorizons literature.**



Before beginning any implant surgical procedure with BioHorizons implants:

- Read and understand the Instructions for Use that accompany the products.
- Clean and sterilize the surgical tray and instruments per Instructions for Use.
- Become thoroughly familiar with all instruments and their uses.
- Study Surgical Kit layout and iconography.
- Design a surgical treatment plan to satisfy the prosthetic requirements of the case.



Small diameter implants with angled abutments are intended for the anterior region of the mouth and are not intended for the posterior region of the mouth due to possible failure of the implant.

Indications for Use

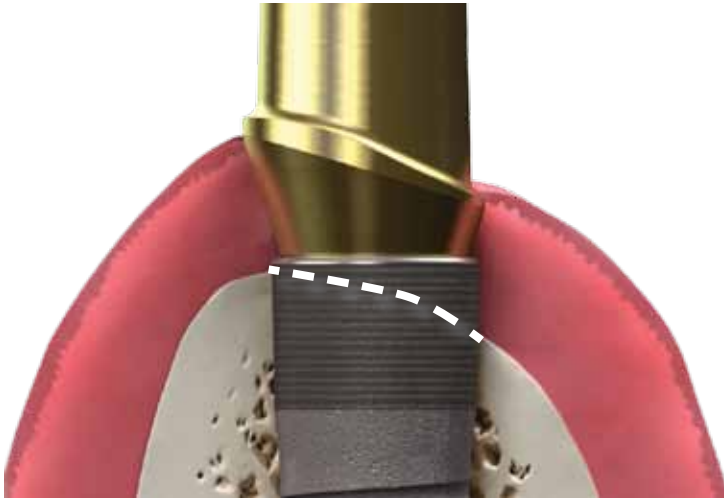
Laser-Lok 3.0 Implants may be used as an artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. The implants may be restored immediately:

- (1) with a temporary prosthesis that is not in functional occlusion,
- (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
- (3) for denture stabilization using multiple implants in the anterior mandible and maxilla.

The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

Implant Placement

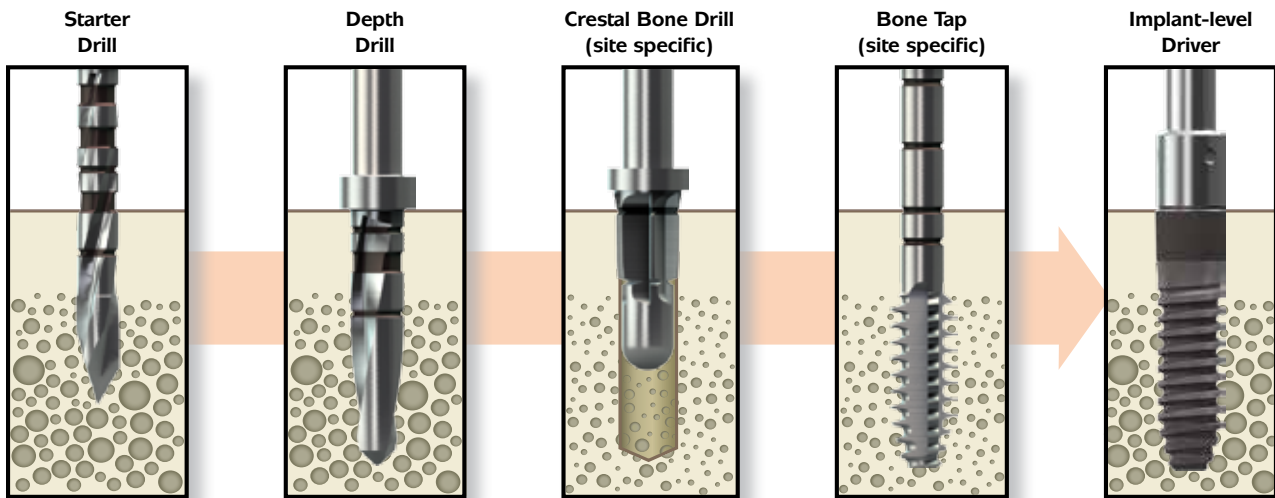
The Laser-lok zone provides 2.1 mm of placement flexibility so placement depth can be driven primarily by the restorative need.



Placement in Uneven Ridges

When placing the Laser-Lok 3.0 implant in an uneven ridge, prepare the osteotomy and place the implant so that the bone/soft-tissue junction is within the 2.1 mm Laser-Lok transition zone. If the discrepancy is more than 2.1 mm, leveling the ridge can be considered.

Drill Sequence



<p>Starter Drill</p> <p>Used to pierce cortical bone.</p>	<p>Depth Drill</p> <p>Depth Drills with stops correspond to matching implant lengths. Depth Drills without stops are also available.</p>	<p>Crestal Bone Drill (site specific)</p> <p>Used to widen crest for implant. Drill stop is 1mm above the laser mark for uneven ridges or D1 bone.</p>	<p>Bone Tap (site specific)</p> <p>Tap required in dense bone; stop when resistance gives or desired depth is reached.</p>	<p>Implant-level Driver</p> <p>Place implant matching the length of the prepared osteotomy.</p>
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Spacing considerations for Laser-Lok 3.0 implants (measurements are taken at the osseous crest)

The osteotomy centerpoint required to maintain a 1.5mm implant-to-tooth spacing (generally accepted) is $\frac{1}{2}$ [implant body diameter] + 1.5mm.

Osteotomy center 3.0mm from adjacent tooth

body diameter	osteotomy center from adjacent tooth
3.0mm	3.0mm

The osteotomy center-to-center measurement required to maintain a 3.0mm edge-to-edge spacing (generally accepted) between Laser-Lok 3.0 implants is $\frac{1}{2}$ [sum of 2 implant body diameters] + 3.0mm.

Measurement is dependent on the two implant body diameters.

platform diameter	Laser-Lok 3.0	Internal & Tapered Internal platform		
	3.0mm	3.5mm	4.5mm	5.7mm
implant center to center	6.0mm	6.3mm	6.8mm	7.4mm



During implant placement, clinicians must apply their best judgment as to the appropriate spacing for individual patient conditions.

Important Considerations

- Peri-operative oral rinses with a 0.12% Chlorhexidine Digluconate solution have been shown to significantly lower the incidence of post-implantation infectious complications.¹⁴ A preoperative 30-second rinse is recommended, followed by twice daily rinses for two weeks following surgery.
- Drilling must be done under a constant stream of sterile irrigation. A pumping motion should be employed to prevent over-heating the bone. Surgical drills and taps should be replaced when they are worn, dull, corroded or in any way compromised. BioHorizons recommends replacing drills after 12 to 20 osteotomies.¹⁵
- There is a risk of injury to the mandibular nerve associated with surgical drilling in posterior mandibular regions. To minimize the risk of nerve injury, it is imperative that the clinician understands the drill depth markings as they relate to the implant length to produce the desired vertical placement of the implant.

All BioHorizons surgical drills are externally irrigated and designed to be used at drill speeds of 850-2500 rpm¹⁶ with sterile irrigation. Reduced drill speed may be indicated in softer bone or as drill diameter increases. In knife-edge residual alveolar ridges, a round bur can be used to create a flat starting point for the starter drill.

2.0mm Extended Shank Starter Drill



Purpose: Initiates osteotomy.

- Chisel-tip design eliminates “skating” on osseous crest
- Initiates osteotomy
- Prepares site for Paralleling Pins

2.5mm Extended Shank Depth Drills

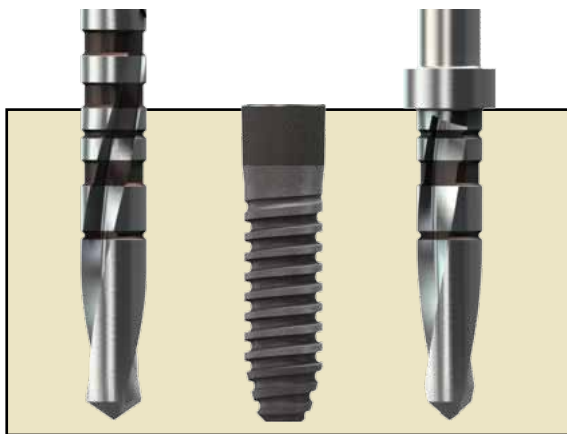


Purpose: Sets osteotomy depth following use of the 2.0mm Extended Shank Starter Drill.

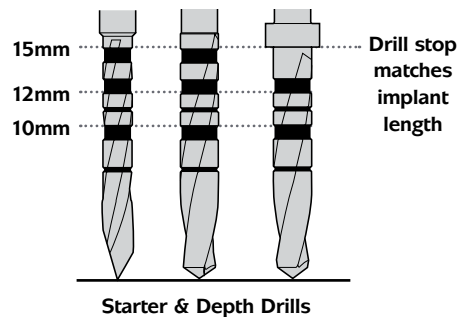
- Efficient cutting drill design collects bone for autografting

Depth Drills with Stops

- Fixed circular ring acts as a definitive drill stop



The 2.0mm and 2.5mm Extended Shank Depth Drills are designed to increase and/or set the depth of the osteotomy.



Parallel Pins



Purpose: Evaluation of osteotomy position and angle.

- Provided straight or with a 20° angle
- Used after 2.0mm Starter Drill and 2.5mm Depth Drills
- 9mm shank for radiographic evaluation of proximity to adjacent anatomy
- Hub diameter is 4.0mm



FINAL BONE PREPARATION

Crestal Bone Drill



Purpose: Removes cortical bone at ridge crest to facilitate pressure-free seating of the implant collar.

- Rounded non-end cutting hub centers drill in osteotomy
- Used following the final drill
- Drill stop is 1mm above the laser mark for uneven ridges or D1 bone



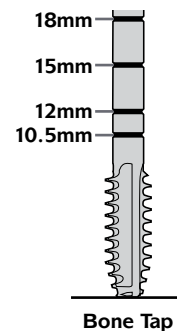
Bone Tap



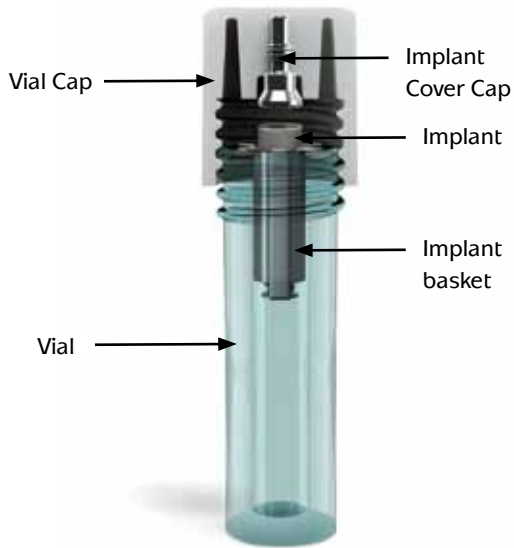
Purpose: Prepares dense cortical bone for implant threads.

- 30 rpm or less¹⁷
- Final instrument prior to implant placement
- Can be driven with a handpiece or ratchet

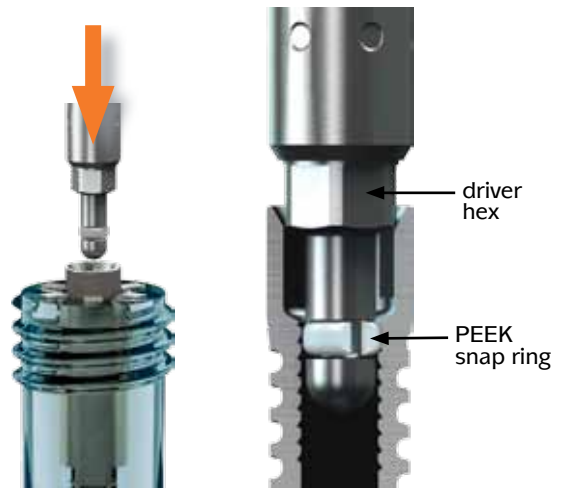
Place the tip of the Bone Tap into the osteotomy, apply firm apical pressure and begin rotating slowly in a clockwise direction (30 rpm or less is recommended)¹⁷. When the threads engage, allow the tap to feed without excessive pressure. To remove, rotate the Bone Tap in a counter-clockwise direction, allowing it to back out of the osteotomy. *Do not pull on the Bone Tap to remove it from the site.*



Implant pickup



The Implant Cover Cap for a two-stage surgical protocol is mounted in the vial cap.



Engage the implant internal hex with an Implant-level Driver. If the driver hex does not engage the implant hex, the plastic snap ring WILL secure the implant for transport to the osteotomy. Excess pressure can deform the implant basket and should be avoided.

Implant placement



Place the apex of the implant into the osteotomy and begin rotating slowly. The driver hex will engage when the driver is slowly rotated under apical pressure. If too much resistance is felt during insertion, remove the implant and revise the osteotomy with the appropriate Crestal Bone Drill or Bone Tap as deemed necessary to reduce insertion torque.

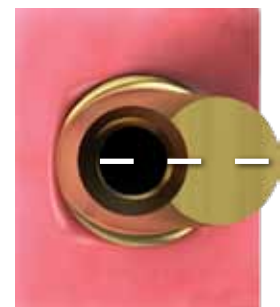
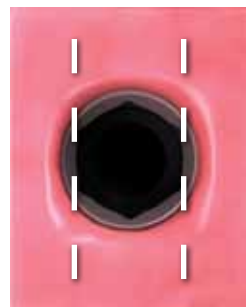


Given the mechanical limitations of small diameter implants, do not exceed 70Ncm of insertion torque. Doing so may damage the implant. Using a torque-limiting handpiece and torque wrench is strongly recommended.

Implant orientation



When seating the implant, use the corresponding dimples on the driver to orient one internal hex flat facially. Doing so verifies that an angled abutment will correct the angulation.



HEALING PROTOCOLS & PROVISIONALIZATION

Cover Caps for two-stage protocol



Purpose: Protects prosthetic platform in two-stage (submerged) surgical protocols.

- Irrigate implant to remove blood and other debris
- Remove Cover Cap from implant vial cap with .050" (1.25mm) Hex Driver
- Thread clockwise into implant body
- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver



An antibacterial paste may be placed on the end of the Cover Cap to help decrease the risk of bacterial growth within the implant body during the healing phase. Following placement of the Cover Cap, the surgical site should be irrigated and the soft tissue adapted in a normal surgical fashion. Take precautions to prevent the Cover Cap from being aspirated by the patient.

Healing Abutments for one-stage protocol



Purpose: Transmucosal element for developing soft tissue emergence.

- Hand-tighten (10-15 Ncm) utilizing .050" (1.25mm) Hex Driver
- Available in two heights: 3mm and 5mm
- Cover cap that comes with implant can be used as 1mm Healing Abutment



Healing Abutments are placed after uncovering in a two-stage surgical protocol, or in lieu of a Cover Cap in a single-stage (non-submerged) protocol. Prior to seating the Healing Abutment, thoroughly irrigate the inside of the implant to remove blood and other debris. An antibacterial paste may be placed on the screw portion to decrease the risk of bacterial growth within the implant body during the healing phase. Following seating, irrigate the surgical site and adapt the soft tissue in normal surgical fashion. A gingivectomy or apically positioned flap technique may be used to reduce the soft tissue thickness and to decrease sulcular depth around the implant. The suture groove on the Healing Abutment may be used to apically position the soft tissue flap. Take precautions to prevent the Healing Abutment from being aspirated by the patient.

Immediate provisionalization

Straight abutments can be modified for fabrication of a cement or screw-retained provisional restoration. A Direct Coping Screw (PXDCS, purchased separately) may be used to maintain a screw access hole during the fabrication of a screw-retained provisional prosthesis.



All Laser-Lok 3.0 abutments are internally threaded for increased strength and come packaged with the abutment screw pre-assembled in the abutment. Partially insert the abutment into the implant and tighten the abutment screw with an .050" (1.25mm) Hex Driver to complete the seating.

Laser-Lok 3.0 implants may be restored immediately:

- (1) with a temporary prosthesis that is not in functional occlusion,
- (2) when splinted together as an artificial root structure for multiple tooth replacement of mandibular incisors, or
- (3) for denture stabilization using multiple implants in the anterior mandible and maxilla.



The implants may be placed in immediate function when good primary stability has been achieved and with appropriate occlusal loading.

POST-OPERATIVE INSTRUCTIONS & ICON LEGEND

Post-operative Instructions

A period of unloaded healing time is often recommended. This is dependent on individual patient healing rates and bone quality of the implant site. Each case must be independently evaluated. This unloaded healing period allows for integration between the bone and implant surface.

The patient must be instructed to follow a post-surgical regimen including cold packs for 24 hours post-implantation. The patient's diet should consist of soft foods and possibly dietary supplements. Pharmacological therapy should be considered as the patient's condition dictates.

If a removable prosthesis is used during the initial healing phase, it is recommended that a soft liner material be used to prevent pressure on the surgical site. The prosthesis should be relieved over the implant site prior to the soft liner application. The patient should be checked periodically to monitor healing of the soft tissues and bone using clinical and radiographic evaluations.

Ongoing hygiene for the implant patient is vital. Hygiene recall appointments at three month intervals are suggested. Instruments designed for implant abutment scaling, such as Implacare™ instruments from Hu-Friedy® should be utilized. The stainless steel handles may be fitted with assorted tip designs used for hygiene on natural teeth. The Implacare® scalers contain no glass or graphite fillers that can scratch titanium implant abutments.

Product Labeling

**3.0 x 12mm
Laser-Lok 3.0 Implant**

BIOHORIZONS®
Birmingham, AL 35244 USA

REF TP312L

LOT YYXXXXX

Laser-Lok, RBT
3.0 x 12mm

STERILE IR Sterile by gamma irradiation

NON-STERILE Non-sterile

Rx Only Caution: Federal (USA) law restricts these devices to the sale, distribution and use by, or on the order of, a dentist or physician.

Artwork label number

REF Reference/article number

LOT Lot/batch number

Single use only

Refer to Instructions for Use

CE BioHorizons products carry the CE mark and fulfill the requirements of the Medical Devices Directive 93/42/EEC

0473

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ORDERING & WARRANTY INFORMATION

BioHorizons No Exceptions Lifetime Warranty on Implants and Prosthetics: All implants and prosthetic components (when used with BioHorizons components) include a No Exceptions Lifetime Warranty. Implant or prosthetic components will be replaced if removal of that product is due to failure (excluding normal wear to overdenture attachments).

Additional Warranties: BioHorizons warranties instruments, surgical drills, taps, torque wrenches and Virtual Implant Placement (VIP) treatment planning software.

(1) Surgical Drills and Taps: Surgical drills and taps include a warranty period of ninety (90) days from the date of initial invoice. Surgical instruments should be replaced when they become worn, dull, corroded or in any way compromised. Surgical drills should be replaced after 12 to 20 osteotomies.¹⁵

(2) Instruments: The BioHorizons manufactured instrument warranty extends for a period of one (1) year from the date of initial invoice. Instruments include drivers, sinus lift components, implant site dilators and BioHorizons tools used in the placement or restoration of BioHorizons implants.

(3) VIP treatment planning software: VIP treatment planning software warranty extends for a period of ninety (90) days from the date of initial invoice. The warranty requires that VIP be used according to the minimum system requirements.

(4) Compu-Guide surgical templates: Compu-Guide surgical templates are distributed without making any modifications to the submitted Compu-Guide Prescription Form and VIP treatment plan ("as is"). BioHorizons does not make any warranties expressed or implied as it relates to surgical templates.

Return Policy: Product returns require a Return Authorization Form, which can be acquired by contacting Customer Care. The completed Return Authorization Form should be included with the returned product. For more information, please see the reverse side of the invoice that was shipped with the product.

Grafton® DBM, MinerOss®, Mem-Lok®, Laddec® must be returned within ten (10) days of initial invoice. AlloDerm® and AlloDerm® GBR™ may not be returned or exchanged for credit due to storage requirement guidelines.

Disclaimer of Liability: BioHorizons products may only be used in conjunction with the associated original components and instruments according to the Instructions for Use (IFU). Use of any non-BioHorizons products in conjunction with BioHorizons products will void any warranty or any other obligation, expressed or implied.

Treatment planning and clinical application of BioHorizons products are the responsibility of each individual clinician. BioHorizons strongly recommends completion of postgraduate dental implant education and adherence to the IFU that accompany each product. BioHorizons is not responsible for incidental or consequential damages or liability relating to use of our products alone or in combination with other products other than replacement or repair under our warranties.

Compu-Guide surgical templates are ordered under the control of a Clinician. The Clinician recognizes responsibility for use. Therefore, regardless of the real or proven damages, the liability to BioHorizons is limited to the price of the product directly related to the reason for the claim.

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Availability: Not all products shown or described in this literature are available in all countries.

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